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10/753,976	01/07/2004	Siau-Way Liew	3155/121	6434

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EXAMINER	
RAMIREZ, JOHN FERNANDO	
ART UNIT	PAPER NUMBER
3737	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,976	LIEW ET AL.	
	Examiner	Art Unit	
	JOHN F. RAMIREZ	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant alleges that Grunkin et al. fail to teach or suggest determining and combining the parameters required by claim 1 (e.g., micro-structural, macroanatomical, and biomechanical) to predict the risk of bone or articular disease. However, the examiner of record disagrees with applicant's assertions. In column 4 lines 35-63, the specifications of the Grunkin et al. patent specifically states:

> According to the first aspect of the present invention, local image intensity information and variation in the local intensity are utilized to extract information relating to the trabecular structure of the part of the bone. In, e.g., digitized radiographic images, local image intensity information may be the individual pixel values, whereas variation in the local intensity is related to the textural information contained in, e.g., inhomogeneities in the image data.
>
> The extracted features resulting from the image manipulation and feature extraction procedure quantify properties of the trabecular structure and, thus, of the bone quality. The extracted features are subsequently introduced into an estimation procedure in which a predetermined relationship between features and bone quality enables the estimation procedure to estimate the bone quality of the vertebrate.
>
> In the present context, to "emphasize" information, such as magnitude information, means to give prominence to prevailing frequency information. This may be performed by either enhancing the prominent information or by reducing the less dominant information—optionally both.
>
> According to the first aspect of the invention, an estimate of the bone quality is obtained in an estimation procedure on the basis of a predetermined relationship between features obtained and reference bone quality parameters. This predetermined relationship is typically established through statistical modelling, where explanatory variables (image features and optionally other explanatory features relating to the bone quality) are used to model corresponding reference bone quality data (response variable).

Based on the above evidence, the method disclosed by Grunkin et al. teach the step of determining and combining the parameters required by claim 1 (e.g., micro-

structural, macroanatomical, and biomechanical) to predict the risk of bone or articular disease. Therefore, the rejection is maintained and also a new rejection is made to claim 1 using prior art Jiang et al. previously presented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-10, 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Grunkin et al. (US 5,915,036).

Grunkin et al. discloses a method for analyzing bone wherein the strength of the bone is estimated. Multiple variables, including micro-structural parameters (col. 4, lines 5-14), macro-anatomical parameters and biomechanical parameters (see claim 33, col. 10, lines 25-29) of a vertebrate were analyzed and evaluated based on x-ray imaging information relating to the trabecular structure to determine the strength of bone and thus the likelihood of risk of future fracture (see abstract, col. 1, lines 3-7,). Bone strength is measured by evaluating the plasticity and maximum load of a bone in a stress-strain diagram (col. 11, lines 18-29, see col. 11, line 40 - col. 12, line 16). An x-ray image is taken of the bone structure and this image is used to determine parameters of an estimated volumetric structure of the bone such as Bone Mass Density and other

parameters related to the-strength of the bone (abstract, col. 1, line 27-49, col. 4, lines 55-67).

Claims 1, 6-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jiang et al. (US 5,915,036).

Jiang discloses a method of predicting bone disease in a subject (see abstract), the method comprising the steps of: determining one or more micro-structural parameters (see abstract, col. 3, lines 5-20), one or more macroanatomical parameters(see abstract, figs. 4A, 7), and one or more biomechanical parameters of a joint in said subject (see col. 15, lines 19-31), wherein determining includes extracting trabecular micro-structure from an image of said subject (col. 3, lines 5-20); and combining the parameters to predict the risk of bone or articular disease, the parameters including a micro-structural parameter, a macro-anatomical parameter, and a biomechanical parameter (see abstract, col. 3 , lines 38-56, see fig. 1B). Jiang et al. teach a method for analyzing bone wherein the strength of the bone is estimated. Multiple variables, including population data such as age of the patient, were used to determine the strength of bone and thus the likelihood of risk of future fracture (abstract, col. 6 lines 27-65; col. 17 lines 15-47; col. 20 lines 22-42; col. 7, lines 29-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunkin et al. (US 5,915,036) in view of Jiang et al. (US 6,442,287).

Grunkin et al. discloses a method for estimating the bone quality of a vertebrate that obtains bone information data and subjects the data to a statistical analysis and provides an output model (see claim 1). Grunkin et al. discloses a specific example of the use of his method is to determine volumetric structure of the bone such as Bone Mass Density and other parameters related to the-strength of the bone (abstract, col. 1, line 27-49, col. 4, lines 55-67). Although, Grunkin et al. does not explicitly disclose comparing the parameters to data derived from a reference database of known disease parameters. In the same field of endeavor, Jiang et al. teach a method for analyzing bone wherein the strength of the bone is estimated. Multiple variables, including population data such as age of the patient, were used to determine the strength of bone and thus the likelihood of risk of future fracture (abstract, col. 6 lines 27-65, col. 17 lines 15-47, col. 20 lines 22-42, col. 7, lines 29-45). It would be obvious to one skilled in the art at the time of the invention to modify the method disclosed by Grunkin with the above discussed enhancements as taught by Jiang et al. in order to provide more accurate results in estimating bone strength by merging and comparing information on bone mass, bone geometry, bone structure and subject age.

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumagai (US 6,306,822 B 1) in view of Grunkin.

Kumagai discloses a method for treating or preventing any condition associated with bone loss through administering an agent to the subject. The bone quality measurement is first measured on day 0, before treatment begins, then again on day 45 and day 90. The bone quality is then compared, showing the effectiveness of each of the agents on remodeling the bone (fig. 5, col. 13, lines 60-63). Kumagai does not disclose the specifics on how they measure the bone density. It would be obvious to one skilled in the art at the time of the invention to use any method that is well known in the art such as the method that is disclosed in Grunkin, which is explained above.

Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunkin et al. (US 5,915,036).

Grunkin et al. discloses a method for analyzing bone wherein the strength of the bone is estimated. Multiple variables, including micro-structural parameters (col. 4, lines 5-14), macro-anatomical parameters and biomechanical parameters (see claim 33, col. 10, lines 25-29) of a vertebrate were analyzed and evaluated based on x-ray imaging information relating to the trabecular structure to determine the strength of bone and thus the likelihood of risk of future fracture (see abstract, col. 1, lines 3-7,). However, Grunkin et al. does not specifically disclose the steps in which the parameters used are selected from the group consisting of total cartilage volume as claimed in claim 20 and from the group of a volume of bone marrow as claimed in claim 21. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the method of Grunkin by replacing the trabecular parameters to

determine the strength of bone and thus the likelihood of risk of future fracture with information relating to the cartilage volume parameters and bone marrow volume parameters as describe in claims 21 and 23, since it has been held that the substitution of known equivalent structures is not patentable unless a new and unexpected result is produced.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

/J. F. R./
Examiner, Art Unit 3737